IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS CORPORATION, NOVARTIS AG, and NOVARTIS PHARMA AG Plaintiffs, v. ACTAVIS, INC. and ACTAVIS ELIZABETH LLC Defendants.	)	Civil Action No. 12-366-RGA-CJB

REPORT AND RECOMMENDATION

In this Hatch-Waxman action filed by Plaintiffs Novartis Pharmaceuticals Corporation, Novartis Corporation, Novartis AG, and Novartis Pharma AG ("Novartis" or "Plaintiffs") against Defendants Actavis, Inc. and Actavis Elizabeth LLC[1] ("Actavis" or "Defendants"), Plaintiffs allege infringement of U.S. Patent Nos. 6,465,504 (the "'504 Patent") and 6,596,750 (the "'750 Patent") (collectively, the "patents-in-suit"). Presently pending before the Court is Defendants' Motion for Judgment of Non-Infringement of the '750 Patent, filed pursuant to Federal Rule of Civil Procedure 12(c), which seeks entry of judgment on the pleadings on Count II of the Complaint (the "Motion"). (D.I. 20) For the reasons that follow, I recommend that Defendants' Motion be DENIED.

I. BACKGROUND

A. The Parties

Novartis Pharmaceuticals Corporation is a Delaware corporation with its principal place

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[1] Plaintiffs also originally brought suit against Actavis Group hf. and Actavis Group PTC ehf., but those parties were later dismissed. (D.I. 13)

of business in East Hanover, New Jersey. (D.I. 1 at ¶ 2) Novartis Corporation is a New York corporation with its principal place of business in New York, New York. (*Id.* at ¶ 3) Novartis AG and Novartis Pharma AG are Switzerland corporations with principal places of business in Basel, Switzerland. (*Id.* at ¶¶ 4–5) Novartis is the owner of the patents-in-suit. (D.I. 17 at ¶¶ 9–10)

Actavis, Inc. ("Actavis U.S.") is a Delaware corporation with its principal place of business in Morristown, New Jersey. (D.I. 14 at ¶ 10) Actavis Elizabeth LLC, a wholly owned subsidiary and agent of Actavis U.S., is a Delaware corporation with its principal place of business in Elizabeth, New Jersey. (*Id.* at ¶¶ 11, 12) Both Actavis corporations are engaged in the business of developing, manufacturing, and distributing generic versions of branded drug products throughout the United States. (*Id.* at ¶¶ 11, 13)

B. The '750 Patent

The '750 Patent is entitled "Substituted 3,5-Diphenyl-1,2,4-Triazoles and Their Use as Pharmaceutical Metal Chelators" and was issued on July 22, 2003. (D.I. 1, ex. B) The '750 Patent is a method-of-use patent relating to an iron chelator called deferasirox.[2] (D.I. 1, ex. B; D.I. 30 at 4) Claims 1, 3, 6, 9, and 18 of the '750 Patent are independent claims and describe "[a] method of treating diseases which cause an excess of metal in a human or animal body or are caused by an excess of metal in a human or animal body . . . ." (D.I. 1, ex. B, col. 27:19–34:42; D.I. 17 at ¶ 27) Among the other claims of the '750 Patent are Claims 8 and 16, which recite "[a]

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[2] Iron chelators are molecules that cause iron to be removed from the body. (D.I. 30 at 4)

method of treating iron overload . . . ." and refer back to claims 3 and 9, respectively.[3] (*Id.* at col. 30:36 & col. 32:57)

C. Plaintiffs' Complaint

This case arises out of Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 203560 to the United States Food and Drug Administration ("FDA"), which seeks approval to market a generic version of EXJADE®, a brand-name drug. (D.I. 1 at ¶ 1) Novartis is the owner of approved New Drug Application No. 21-882, which covers EXJADE®. (*Id.* at ¶ 27) EXJADE® is deferasirox in tablet form for oral suspension. (*Id.* at ¶ 1) Novartis has listed the '504 Patent[4] and the '750 Patent in the Orange Book as covering EXJADE®.[5] (*Id.* at ¶ 27)

Plaintiffs filed suit against Defendants on March 21, 2012, (D.I. 1), alleging that Defendants' submission of ANDA No. 203560 infringes at least one claim of each of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A). (*Id.* at ¶¶ 33, 38) Further, Plaintiffs allege that upon FDA approval of Defendants' ANDA, Defendants will infringe the patents-in-suit in violation of 35 U.S.C. § 271(a)-(c) by making, using, offering to sell, and selling its generic deferasirox product and by actively inducing and contributing to infringement by others. (*Id.* at ¶¶ 34, 39) Plaintiffs seek, *inter alia*, a permanent injunction barring Defendants from manufacturing, using,

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[3] While Defendants have characterized claims 8 and 16 as dependent claims, (D.I. 14 at 18, at ¶ 29; D.I. 21 at 9), Plaintiffs have denied this and assert that the claims are independent, (D.I. 17 at ¶ 29).

[4] The '504 Patent is not at issue in Defendants' Motion. Certain claims of that patent recite the compound deferasirox. (D.I. 21 at 1; D.I. 30 at 5)

[5] *See infra* Section III.A for a more detailed discussion of the ANDA process pursuant to the Hatch-Waxman Act.

selling, or offering to sell in the United States, or importing into the United States, any deferasirox product that infringes valid claims of the patents-in-suit until after the latest expiration date of those patents. (*Id.* at 10, at ¶ 3)

D. Procedural History

Defendants filed their Answer and Counterclaims on May 1, 2012. (D.I. 14) One of Defendants' counterclaims is a request for an order requiring Plaintiffs to de-list the '750 Patent from the Orange Book for EXJADE® on the ground that the patent does not claim an approved use for the drug. (D.I. 14 at 17–18, at ¶¶ 25–33) Plaintiffs filed their Answer to Defendants' Counterclaims on May 22, 2012. (D.I. 17)

On May 31, 2012, Defendants filed the instant Motion. (D.I. 20) On June 6, 2012, this case was referred to me by Judge Richard G. Andrews to hear and resolve all pretrial matters up to and including case-dispositive motions. Defendants' Motion was fully briefed as of July 16, 2012, (D.I. 37), and on October 4, 2012, the Court heard oral argument regarding the Motion. The Motion is now ripe for decision.

II. STANDARD OF REVIEW

Pursuant to Federal Rule of Civil Procedure 12(c) ("Rule 12(c)"), a party may move for judgment on the pleadings "[a]fter the pleadings are closed—but early enough not to delay trial . . ." Fed. R. Civ. P. 12(c). Courts evaluating Rule 12(c) motions may grant judgment on the pleadings, thereby disposing of one or more claims in a lawsuit, if "'the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law.'" *Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008)

(quoting *Jablonski v. Pan Am. World Airways, Inc.*, 863 F.2d 289, 290–91 (3d Cir. 1988)).[6] In deciding whether judgment on the pleadings is appropriate, courts may consider the pleadings, corresponding exhibits thereto, and documents incorporated by reference. *Butamax Advanced Biofuels LLC v. Gevo, Inc.*, No. 11-54-SLR, 2012 WL 2365905, at *1 (D. Del. June 21, 2012).

Rule 12(c) motions are reviewed under the same standards as motions to dismiss filed pursuant to Fed. R. Civ. P. 12(b)(6). *Galderma Labs. Inc. v. Amneal Pharm., LLC*, No. 11-1106-LPS, 2012 WL 3890942, at *1 (D. Del. Sept. 7, 2012) (citing *Citisteel USA, Inc. v. Gen. Elec. Co.*, 78 F. App'x 832, 835 n.3 (3d Cir. 2003)); *see also Butamax*, 2012 WL 2365905, at *1. Accordingly, courts must accept all factual allegations in a complaint as true and view them in the light most favorable to the nonmoving party. *Butamax*, 2012 WL 2365905, at *1.

III. DISCUSSION

A. ANDA Procedures Under the Hatch-Waxman Act

The Hatch-Waxman Act (the "Act"), codified as amended at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271 and 282, strikes a balance between the competing policy interests of "(1) inducing pioneering research and development of new drugs and (2) enabling competitors to

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[6] In a patent case, the procedural law of the regional circuit (here, the United States Court of Appeals for the Third Circuit) dictates the standard of review applicable to Rule 12(c) motions. *Allergan, Inc. v. Athena Cosmetics, Inc.*, 640 F.3d 1377, 1380 (Fed. Cir. 2011); *Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc.*, 482 F.3d 1317, 1320 (Fed. Cir. 2007). However, to the extent that a court must review "substantive patent law embodied in the pleadings" to decide a Rule 12(c) motion, Federal Circuit law applies. *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1327 (Fed. Cir. 2012) (Newman, J., dissenting); *see also Illinois Computer Research LLC v. Harper Collins Publishers, Inc.*, No. 10 Civ. 9124 (PAC), 2011 WL 3279065, at *2 (S.D.N.Y. July 28, 2011) (applying Federal Circuit law in considering a Rule 12(c) motion as to substantive patent issues and regional circuit law as to certain procedural issues); *Gelsomino v. Horizon Unlimited, Inc.*, No. 07-80697-CIV, 2008 WL 4194842, at *2 (S.D. Fla. Sept. 10, 2008) (same).

bring low-cost, generic copies of those drugs to market." *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370–71 (Fed. Cir. 2002). Pursuant to the Act, a drug manufacturer seeking FDA approval to market the generic form of a previously approved drug for an approved use may submit an Abbreviated New Drug Application ("ANDA"), rather than submitting a full New Drug Application ("NDA"). *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1318 (Fed. Cir. 2012); *see also Astrazeneca Pharm. LP, IBR v. Apotex Corp.*, No. 10-388 (RBK/KW), 2010 WL 5376310, at *2 (D. Del. Dec. 22, 2010). The ANDA process circumvents the lengthy approval scheme in place for NDAs by permitting generic manufacturers to depend on the safety and efficacy studies completed for the previously approved drug, so long as there is bioequivalency between the generic drug and the previously approved drug. *Bayer*, 676 F.3d at 1318; *see also Astrazeneca*, 2010 WL 5376310, at *2.

To allow for prompt judicial determination of whether an ANDA applicant's drug or method of using the drug infringes a valid patent, the Act dictates that the filing of an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent" is itself "an act of infringement." 35 U.S.C. § 271(e)(2)(A); *see also Bayer*, 676 F.3d at 1318. The artificial act of infringement created by the ANDA filing establishes the court's jurisdiction to decide a drug manufacturer's patent infringement action against the generic manufacturer. *Bayer*, 676 F.3d at 1318.

In line with its goals of protecting patentees and facilitating approval of generic drugs, the Act dictates that a pharmaceutical manufacturer obtaining FDA approval for a new drug must identify every patent relating to the drug "with respect to which a claim of patent infringement could reasonably be asserted." 21 U.S.C. § 355(b)(1); *see also Bayer*, 676 F.3d at 1318. The

FDA identifies these patents in a publication called *Approved Drug Products with Therapeutic Equivalence Evaluations*, universally referred to in the industry as the "Orange Book." *Bayer*, 676 F.3d at 1318.

An ANDA applicant is required to consult the Orange Book and take action relating to all pertinent patents. *Id.* Accordingly, if an applicable method-of-use patent exists that is set to expire after the release of the generic drug, the applicant must accompany its ANDA with either a "section viii statement" or a "paragraph IV certification." *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 U.S.C. § 355(j)(2)(A)(viii); *see also Bayer*, 676 F.3d at 1318–19.

A section viii statement indicates that the applicant wants to market the generic drug for a different method of use than those claimed by relevant patents listed in the Orange Book. 21 U.S.C. § 355(j)(2)(A)(viii); *see also Bayer*, 676 F.3d at 1318; *Astrazeneca*, 2010 WL 5376310, at *2. The Federal Circuit has described such statements as "carve-outs" because they "limit[] the scope of the generic manufacturer's ANDA to approved indications that are not claimed by valid patents listed in the Orange Book." *Astrazeneca*, 2010 WL 5376310, at *2. Accordingly, an ANDA applicant should *not* file a section viii statement when "the ANDA applicant is seeking approval for exactly the same labeling as that in the NDA for which the patent was submitted." *Bayer*, 676 F.3d at 1318 (quoting Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,682 (June 18, 2003)).

When a section viii statement is not appropriate, the ANDA applicant must file a "paragraph IV certification," which is used to assert that the patent "is invalid or will not be infringed by the manufacture, use, or sale" of the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also Bayer*, 676 F.3d at 1319. The ANDA applicant must then send a

notice letter to the holder of the original NDA and the patent owner, 21 U.S.C. § 355(j)(2)(B), receipt of which triggers a forty-five day window for the patent holder to file a patent infringement lawsuit. 21 U.S.C. § 355(j)(5)(B)(iii); *see also Astrazeneca*, 2010 WL 5376310, at *3. Upon commencement of a patent infringement lawsuit, a thirty-month stay of approval of the ANDA is put in place, running from the date of the patentee's receipt of the notice letter. 21 U.S.C. § 355(j)(5)(B)(iii); *see also Astrazeneca*, 2010 WL 5376310, at *3.

For a method-of-use patent, this "artificial" infringement claim lies only against a patented use that has been approved by the FDA. *Bayer*, 676 F.3d at 1319. Under 21 U.S.C. § 355(j)(2)(A)(i), an ANDA may not seek approval for an unapproved or off-label use of a drug; thus, it necessarily follows that 35 U.S.C. § 271(e)(2)(A) does not apply to a use patent claiming only such a use. *Id.* (citations omitted).

In this matter, Plaintiffs had filed an NDA triggering FDA approval "for the marketing and sale of 125 mg, 250 mg and 500 mg strength deferasirox tablets for oral suspension." (D.I. 1 at ¶ 27) Plaintiffs branded the drug as EXJADE®. (*Id.*) In accordance with the requirements of the Act, Plaintiffs identified two patents relating to EXJADE® for listing in the Orange Book: the '504 Patent, which describes the active ingredient in EXJADE®, and the '750 Patent, which describes, the Plaintiffs assert, "at least one method of using EXJADE®." (D.I. 30 at 5; *accord* D.I. 1 at ¶ 27)

Pursuant to the Act, Defendants furnished Plaintiffs with a February 7, 2012 notice letter that disclosed Defendants' submission of ANDA No. 203560 to the FDA for approval to manufacture and market the generic form of EXJADE® prior to the expiration of the patents-in-suit. (D.I. 1 at ¶ 28) The letter also disclosed that Defendants included a paragraph IV

certification in the ANDA "asserting that the '504 and '750 Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of Actavis's 125 mg, 250 mg, and 500 mg generic deferasirox tablets for oral suspension." (*Id.* at ¶ 30)

B. The Parties' Contentions

In their Motion, Defendants argue that Plaintiffs cannot state claims for infringement of the '750 Patent under 35 U.S.C. § 271(e)(2)(A) or 35 U.S.C. § 271(a)-(c). (D.I. 21) Focusing on independent Claims 1, 3, 6, 9, and 18 of the '750 Patent, Defendants note that those claims recite methods of using deferasirox limited to "treating diseases which cause an excess of metal in a human or animal body or are caused by an excess of metal in a human or animal body." (*Id.* at 9–11; D.I. 37 at 3–4) On the other hand, Defendants note, the FDA-approved use for EXJADE®, captured in the "Indications and Usage" section of the drug's label, is for the "treatment of chronic iron overload due to blood transfusions in patients 2 years of age and older." (D.I. 21 at 11; *see also* D.I. 14, ex. A; D.I. 17 at ¶ 30) Defendants' ANDA seeks approval for this same approved indication; accordingly, the "Indications and Usage" section of the proposed label for Defendants' generic version contains identical language to that of the EXJADE® label. (D.I. 14 at 18, at ¶ 30; D.I. 22, ex. 1 at 1) Defendants then argue that the EXJADE® and generic drug labels state one clear indication—treatment of "chronic iron overload due to blood transfusions"—while the '750 Patent states a *different* indication for EXJADE®'s active ingredient, deferasirox—treatment of "diseases" which cause or are caused by an excess of metal. (D.I. 21; D.I. 37)

The essence of Defendants' argument is that "chronic iron overload due to blood transfusions" is not a "*disease[]* which *cause[s]* an excess of metal in a human or animal body or

[is] *caused by* an excess of metal in a human or animal body" but instead amounts to that very "excess of metal" itself. (D.I. 21 at 3–5; D.I. 37 at 1, 5) Therefore, Defendants assert, the proposed method of use for the generic drug that they seek to market is not covered by—and thus cannot infringe—the '750 Patent. (D.I. 21 at 1–2) In Defendants' view, this conclusion is clear on the face of the pleadings and the other associated documents that the Court can examine at this early stage of the litigation; therefore, Plaintiffs' infringement claims relating to the '750 Patent may be properly dismissed at this time. (D.I. 21; D.I. 37)

In response, Plaintiffs argue that for three reasons, Defendants' Motion should be denied. First, Plaintiffs argue that they have "brought a legally cognizable claim for infringement," having pled all of the requisite elements of a patent infringement claim under the Hatch-Waxman Act. (D.I. 30 at 11; *see also id.* at 1) Second, Plaintiffs assert, pointing to evidence in the '750 Patent and from other sources, that Defendants' generic drug does indeed infringe the '750 Patent because the patented method equates to the method of use described in Defendants' proposed labeling. (*Id.* at 1, 11–13) Third, Plaintiffs argue that, regardless of the ultimate merit of its infringement arguments, disposal of its infringement claims relating to the '750 Patent would be premature at this stage of the litigation. (*Id.* at 2–3, 13–14) They assert that such a determination would require the construal of some of the patent's claim terms and (likely) the consideration of extrinsic evidence—processes that should not come into play at the pleadings stage of a case. (*Id.* at 13)

C. Determining Whether Entry of Judgment on the Pleadings Is Appropriate

The Court finds that an entry of judgment on the pleadings in favor of Defendants on Count II of Plaintiffs' Complaint is not appropriate. The Court agrees with Plaintiffs that were it

to grant Defendants the relief they seek, this would first require the Court to determine the proper construction of a claim term of the '750 Patent—a term whose meaning is not clear to the Court at this stage. The grant of Defendants' Motion is therefore inappropriate.

Defendants hinge their argument for disposal of Count II at the pleading stage primarily on a recent case from the Federal Circuit, *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316 (Fed. Cir. 2012). According to the *Bayer* Court, Defendants argue, a Rule 12(c) motion is the "appropriate vehicle" to dispose of a plaintiff's infringement claim regarding a method-of-use patent if the ANDA applicant's proposed method of use is different than the use protected by the patent-in-suit. (D.I. 21 at 8)

In *Bayer*, the defendants sought to market the generic form of Yasmin, an oral contraceptive. 676 F.3d at 1319. Several years earlier, the FDA had approved plaintiffs' predecessor's NDA regarding Yasmin "for oral contraception." *Id.* The defendants filed ANDAs seeking approval from the FDA to market generic forms of Yasmin for that same approved use: "for oral contraception." *Id.* The defendants also filed paragraph IV certifications relating to the three relevant patents listed in the Orange Book. *Id.* The plaintiffs thereafter filed suit against the ANDA applicants, alleging infringement of one of those three patents, a method-of-use patent whose claims recited that the drug "achieves three effects simultaneously: a contraceptive (or gestagenic) effect, an anti-androgenic effect . . . and an anti-aldosterone effect." *Id.* at 1320. In response, the defendants filed a Rule 12(c) motion, arguing that judgment of non-infringement should be entered on the pleadings in their favor because they sought to market the generic form of Yasmin "only for oral contraception and not for the combination of uses claimed in the [] patent." *Id.* The district court agreed, granting defendants' motion. *Id.*

On appeal, the plaintiffs argued that the district court erred because the FDA had in fact approved the use of Yasmin to obtain all three effects simultaneously in certain female patients, and that the ANDAs at issue sought approval for these identical uses, such that defendants were liable for infringement. *Id.* at 1321. In doing so, the plaintiffs did not dispute that the Indications and Usage section of the FDA-approved label only provided for use of the drug as an "oral contraceptive" and that this section of the defendants' proposed labeling referred to the same use (and thus did not make reference to the other two effects claimed by the patent). *Id.* at 1320. Rather, the plaintiffs based their argument in part on the "Clinical Pharmacology" section of the label; because this section referred to the other two effects, the plaintiffs argued, the FDA had approved "the use of Yasmin to induce those effects." *Id.* at 1322, 1324.

The Federal Circuit rejected the plaintiffs' argument. In doing so, it found that the drug's label did not state that the combination of effects claimed in the patent is safe and effective, as required by FDA regulations. *Id.* at 1324. The *Bayer* Court found that a use for a drug is only FDA-approved when the safety and efficacy of that use has been established, and that the inclusion of a use in the Indications and Usage section of a drug label equates to "[a]cknowledgement of the safety and efficacy of that specific method of use." *Id.* Additionally, the *Bayer* Court considered evidence submitted by plaintiffs along with the pleadings (including physicians' declarations and marketing materials). *Id.* Plaintiffs asserted that this evidence showed that the entirety of the labeling indicated that Yasmin was safe and effective for inducing the claimed combination of effects. *Id.* But the *Bayer* Court found that this evidence simply demonstrated that the FDA was aware that Yasmin could cause the other two effects, not that the FDA had approved the safety and efficacy of the claimed combination of effects. *Id.*

Accordingly, the Court held, the FDA had only approved Yasmin for use as an oral contraceptive, and thus the defendants did not commit infringement because they sought to market the generic form solely for that use, while the patent-at-issue covered a different method of use. *Id.* at 1326.

The Court does not find the decision in *Bayer* to be particularly helpful to the resolution of this case. Defendants describe *Bayer* as a case where "the Federal Circuit established that a Court should enter judgment on the pleadings *when it is clear from the pleadings* that the use of the drug for which the ANDA filer is seeking FDA approval is not covered by the asserted patent."[7] (D.I. 37 at 1 (emphasis added)) In *Bayer*, the dispute was whether the label for Yasmin indicated that the FDA had approved the drug for all three of the uses claimed in the patent. The

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[7] Plaintiffs, for their part, attempt to distinguish *Bayer* as a case where "the patent holder (unlike Novartis) *did not dispute* that the Indications and Usage portion of the proposed generic labeling did not refer to the patented use." (D.I. 30 at 11 (emphasis in original)) In fact, precedent suggests that a motion to dismiss can be properly granted where it is not disputed that a party has submitted an ANDA seeking approval to market a drug for uses that are different than the uses covered by the opposing party's method-of-use patent. *See AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1380 (Fed. Cir. 2012) (upholding grant of defendants' motion to dismiss where defendants' ANDAs contained section viii statements that "explicitly and undisputedly carve[d] out" all of the plaintiffs' patented indications for the drug-at-issue). However, in *Bayer*, although it was not disputed that the Indications and Usage portion of the label did not refer to the patented use, there was very much a live dispute between the parties as to whether "the label, taken in its entirety" recommended or suggested to a physician that Yasmin was safe and effective "for inducing the claimed combination of effects in patients in need thereof." *Id.* at 1324. Indeed, it is difficult to glean from *Bayer* how clear the state of the established factual record must be at the pleading stage for a court to grant a Rule 12(c) motion in a case like this. On that point, for example, the dissent in *Bayer* argued that the plaintiff *had* sufficiently alleged facts suggesting that the simultaneous treatment of all three effects was an intended FDA-approved use for Yasmin—and that the district court had wrongly made "contrary findings under Rule 12(c)." *Id.* at 1329 (Newman, J., dissenting). In any event, as is discussed further herein, this case involves a scenario that distinguishes it from *Bayer*, in that the resolution of whether the intended use for Defendants' generic drug is covered by the patent's claims depends on the construction of the patent's claim terms—and very possibly on the introduction of facts and evidence that are not yet before the Court.

resolution of that question did not depend on a court's construction of a term in the patent. In this case, however, the dispute directly relates to the construction of a key term in the relevant patent claims. That dispute is about whether the undisputed FDA-approved use for EXJADE® (captured in the "Indications and Usage" section of the drug's label)—"the *treatment of chronic iron overload due to blood transfusions* in patients 2 years of age and older"—is claimed by the patented method of "treating *diseases* which cause an excess of metal in a human or animal body or are caused by an excess of metal in a human or animal body." (D.I. 17 at ¶ 30; D.I. 1, ex. B, col. 27:19–34:42 (emphasis added); D.I. 22, ex. 1 at 1 (emphasis added)) And the resolution of that question depends quite a lot on what the "diseases" term in the patent *means*.

Resolution of patent infringement allegations involves a two step process: "[t]he court must first interpret the claim and determine the scope and the meaning of the asserted patent claims, and then compare the properly construed claims to the allegedly infringing device." *Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 355 F.3d 1361, 1367 (Fed. Cir. 2004) (citation omitted). This Court and other courts have repeatedly held that if a court is required to construe the meaning of claim terms and perform an infringement analysis in order to resolve a motion to dismiss or a motion for judgment on the pleadings, the motion should be denied, because this type of analysis is inappropriate at the pleading stage.[8] *See, e.g., Butamax*, 2012 WL 2365905, at

[8] Our Court has explained that as to a motion for judgment on the pleadings, this is so because the motion is meant to dispose of claims where the material facts are undisputed, and judgment concerning a question of law can therefore be entered by a court after reviewing the competing pleadings and exhibits thereto. *Butamax*, 2012 WL 2365905, at *1. For this reason, it has specifically noted that a Rule 12(c) motion can be ill-suited to resolving a legal dispute that turns on the interpretation of a patent claim term, since that issue can, in turn, implicate disputed questions of fact. *Id.* at *1 & n.1; *see also Pfizer, Inc. v. Ranbaxy Labs., Ltd.*, 525 F. Supp. 2d 680, 684–85 (D. Del. 2007) (stating that when considering a Rule 12(c) motion, as when considering a Rule 12(b)(6) motion, the Court must "draw all reasonable factual inferences in the

*1; *Tech. Innovations, LLC v. Amazon.com, Inc.*, No. 11-690-SLR, 2012 WL 1441300, at *2 (D. Del. Apr. 25, 2012); *Fujitsu Ltd. v. Belkin, Int'l, Inc.*, 782 F. Supp. 2d 868, 890 (N.D. Cal. 2011); *Deston Therapeutics LLC v. Trigen Labs. Inc.*, 723 F. Supp. 2d 665, 670 (D. Del. 2010); *Yangaroo Inc. v. Destiny Media Techs. Inc.*, No. 09-C-462, 2009 WL 2836643, at *3 (E.D. Wis. Aug. 31, 2009). These courts have reasoned that it is unsuitable to engage in such an inquiry at the pleading stage, because claim construction can be illuminated by the consideration of extrinsic evidence—evidence that is often not before the court at that stage. *See, e.g., Tech. Innovations*, 2012 WL 1441300, at *2; *Fujitsu*, 782 F. Supp. 2d at 890; *Deston Therapeutics*, 723 F. Supp. 2d at 670; *Yangaroo,* 2009 WL 2836643, at *3. They also note that a claim construction analysis at the pleading stage does not benefit from the procedures (including an exchange of discovery documents relating to infringement, the exchange of proposed constructions and extensive briefing) that typically precede a *Markman* hearing. *See, e.g., Tech. Innovations*, 2012 WL 1441300, at *2; *Butamax*, 2012 WL 2365905, at *1; *Fujitsu*, 782 F. Supp. 2d at 890. Moreover, it has been noted that the second comparison step of an infringement analysis is not well suited to resolution on a motion to dismiss, because it too requires the consideration of extrinsic evidence (*i.e.*, evidence regarding the accused device or process) that is often not properly before the Court at that time. *Fujitsu*, 782 F. Supp. 2d at 889–90.

One such case in this Court involving a Rule 12(c) motion was *Butamax Advanced Biofuels LLC v. Gevo, Inc.*, No. 11-54-SLR, 2012 WL 2365905 (D. Del. June 21, 2012). In *Butamax*, two of the defendant's counterclaims alleged that the plaintiff and a counterclaim-defendant infringed two of the defendant's patents. *Id.* at *1. The plaintiff filed a motion for

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light most favorable to the nonmovant").

judgment on the pleadings pursuant to Rule 12(c), arguing that "the only reasonable interpretation[s]" of certain claim language in the patents rendered plaintiff's accused products, recombinant yeast microorganisms, non-infringing. *Id.* at *1 n.1. In denying the motion, this Court reasoned that the plaintiff was effectively asking it to "embrace its characterization of the patents." *Id.* at 1. This Court refused to do so at that early stage of litigation, explaining:

> Given the complex technology at issue and the standard of review, the court finds these counterclaims particularly ill suited for disposition on a motion for judgment on the pleadings. The court declines to tackle the issues of claim construction and infringement without the benefit of any introductions to the technology or to the accused "product" but for Butamax's assertions regarding same.

Id. at *1.[9]

This type of analysis is in line with the reasoning in the Federal Circuit's recent decision in *In re Bill of Lading Transmission and Processing Sys. Patent Litig.*, 681 F.3d 1323 (Fed. Cir. 2012). In that case, the Federal Circuit commented on what role, if any, claim construction

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[9] *Cf. Tech. Innovations*, 2012 WL 1441300, at *1–2 (denying defendant's Rule 12(b)(6) motion seeking dismissal of the plaintiff's claim that the defendant's Kindle product infringed its patent claiming a type of "book" containing a "plurality of pages of printed information," and declining to "engage in a claim construction exercise, construing the claim terms 'book' and 'printed information,' at this stage of the proceedings, with no context provided by discovery or a motion practice"); *Walker Digital, LLC v. Facebook, Inc.*, 852 F. Supp. 2d 559, 562–63 (D. Del. Apr. 4, 2012) (denying defendants' Rule 12(b)(6) motion, filed on the grounds that the accused marketing promotions do not satisfy the claim limitations of the asserted patents, as premature because "the court is not prepared to engage in a claim construction exercise . . . with no context whatsoever provided by discovery or a motion practice"); *Internet Media Corp. v. Hearst Newspapers, LLC*, No. 10-690-SLR, 2011 WL 2559556, at *2–3 (D. Del. June 28, 2011) (denying the defendant's Rule 12(b)(6) motion, filed on the grounds that the patent-at-issue was indefinite as a matter of law, because analysis by the Court "would require the court to construe said claims, an action that is not appropriate in connection with a motion to dismiss"); *Deston Therapeutics*, 723 F. Supp. 2d at 672 (denying defendants' Rule 12(b)(6) motion, which involved disputed claim language, because "[c]laim construction in this case is more complicated than [d]efendants allow and should not be determined at this stage").

should play at the pleading stage of a case. 681 F.3d at 1343 n.13. In reviewing a district court's decision on a motion to dismiss, the *Bill of Lading* Court noted that when such a court considers the plausibility of the facts alleged in a complaint, it should not "base[] its assessment of the 'reasonableness' of a given inference of infringement on a narrow construction of the patent's claims." *Id.* The *Bill of Lading* Court explained that were a district court to engage in "claim construction at the pleading stage—with no claim construction processes undertaken," this would be "inappropriate," noting that "[w]e afford the claims their broadest possible construction at this stage of the proceedings." *Id.*[10]

In this case, Defendants do not argue that Plaintiffs have failed to plead sufficient facts to establish claims of direct and indirect infringement under the requirements of Rule 8 or the Supreme Court's precedent in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) and its progeny. Instead, Defendants argue that dismissal on the pleadings is appropriate because there is no plausible way that the patent's reference to "treating diseases which cause an excess of metal in a human or animal body or are caused by an excess of metal in a human or animal body" can amount to the FDA-approved use of deferasirox for "the treatment of chronic iron overload

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[10] Federal Circuit precedent suggests that there may be certain (perhaps rare) cases where, even when dismissal will turn on the disputed meaning of a claim term, the facts of record at the pleading stage will clearly and explicitly indicate that the moving party should prevail in a manner that could not plausibly be challenged at a later claim construction hearing. In such cases, dismissal may be appropriate. *See, e.g.*, *Desenberg v. Google, Inc.*, 392 F. App'x 868, 871 (Fed. Cir. 2010) (upholding district court's dismissal of plaintiff's direct infringement claim, on grounds that the claim required an allegation of joint infringement that plaintiff had not made, where the district court was presented with evidence that plaintiff had previously amended the claim in a manner that explicitly required the conduct of a joint infringer in order for direct infringement to occur); *see also Deston Therapeutics*, 723 F. Supp. 2d at 671 ("The Court can perhaps envision a patent infringement cause of action for which patent claims could be construed on a motion to dismiss . . . ."). For the reasons discussed below, this is not such a case.

due to blood transfusions in patients 2 years of age and older." At base, Defendants' argument is a simple one. The patented method, they say, relates to the treatment of certain "diseases"—those that "cause an excess of metal . . . or are caused by an excess of metal." (D.I. 37 at 1) But the FDA-approved use-at-issue is for the treatment not of such "diseases," but instead for an underlying *cause or result* of such diseases: "chronic iron overload caused by blood transfusions" (*i.e.*, an "excess of metal" in the blood). (*Id.*)

Perhaps the easiest way to demonstrate that Defendants' motion is premature is to examine a few of Plaintiffs' arguments to the contrary. Plaintiffs assert, *inter alia*, that "iron overload caused by blood transfusion is not only a disease in and of itself, but also causes other diseases when left untreated." (D.I. 30 at 2) In support, Plaintiffs cite to a portion of the patent's specification:

> In other illnesses, in particular of man, an excess of iron occurs in the various tissues. This is designated as iron overload (formerly haemosiderosis). It occurs, e.g., after parenteral administration of iron (especially repeated blood transfusions) or after increased uptake of iron from the gastrointestinal tract.

(D.I. 1, ex. B, col. 1:15–20) Plaintiffs assert that the reference demonstrates that "iron overload" is an "illness[]" (which Plaintiffs equate to a reference to a "disease[]") that occurs after the "administration of iron"—and this indicates that "chronic iron overload due to blood transfusions" is one of the "diseases . . . caused by an excess of metal" referenced in the patent. (D.I. 30 at 12) Defendants, for their part, cite to the same portion of the specification and come to the opposite conclusion: that the specification's reference to "illnesses" (which it also equates to a reference to "diseases") only refers to a disease *being caused by* iron overload—not that the reference to "illnesses" suggests that "chronic iron overload due to blood transfusions" *is itself*

an illness or disease of the type referenced in the claim term-at-issue. (D.I. 37 at 4) The fact that both parties have a reasonable dispute as to how this piece of intrinsic evidence affects the meaning of the claim term-at-issue only underscores for the Court that this issue is a debatable one—one not appropriately resolved at this early stage of the case without the benefit of *Markman* briefing and a *Markman* hearing.

This is underscored to an even more significant degree by another line of Plaintiffs' argument: that the Court does not yet have before it certain other intrinsic and extrinsic evidence that may be important in analyzing the meaning of this claim term. At oral argument, Plaintiffs cited to a portion of the file history that was not otherwise in the record in the case, specifically two articles referenced in the "Other Publications" section of the '750 Patent. (D.I. 57 at 60–61) Plaintiffs pointed to portions of these articles that refer to "iron[-]overload diseases" in suggesting that these references would bolster their claim construction argument. (*Id.*) Plaintiffs also cited, for the same purpose, to one piece of extrinsic evidence not otherwise before the Court: a 1992 article that refers to "iron[-]overload disease" as a byproduct of blood transfusions. (*Id.* at 61–62) And Plaintiffs noted that they may well seek to introduce extrinsic evidence from a person of ordinary skill in the art at a *Markman* hearing, in order to underscore their contention that iron overload due to blood transfusions amounts to a disease and/or that Defendant's proposed construction is not supportable. (*Id.* at 62) The Court's point in referencing these citations or arguments is not to suggest that it has or will find them to be definitive in considering the meaning of the claim term-at-issue. It is only to state that such evidence (or evidence like it) *might* help carry the day, and yet would never be reviewed by the

Court if Plaintiffs' claim were dismissed at this stage.[11]

Ultimately, this is a case where "[c]laim construction . . . is more complicated than Defendants allow and should not be determined at [the pleading] stage." *Deston Therapeutics*, 723 F. Supp. 2d at 672. The Court offers no opinion at this time regarding the meaning of the claim term-at-issue or any other disputed claim terms in the '750 Patent. However, the Court finds that, ascribing the broadest possible meaning to the claim term, Plaintiffs have presented a plausible argument as to why dismissal is inappropriate. The claim construction process, culminating with a *Markman* hearing, was designed to best resolve such arguments. In light of this, and in light of the requirement that the Court draw all reasonable factual inferences in the Plaintiffs' favor at this stage, the Court recommends that Defendants' Motion be denied.[12]

IV. CONCLUSION

For the foregoing reasons, I recommend that the Court DENY Defendants' Motion.

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[11] As noted above, there is also a dispute between the parties as to whether Claim 8 and Claim 16, which recite a "method of treating iron overload," are independent or dependent claims. (D.I. 14 at 18, at ¶ 29; D.I. 21 at 9; D.I. 17 at ¶ 29) It is not, however, seriously disputed that the resolution of this question will have an impact on the force of the arguments behind Defendants' Motion. This type of determination is best left for the *Markman* hearing stage of the case, when the Court will have before it additional argument and (and perhaps evidence) relating to the issue.

[12] The Defendants' recent filing, (D.I. 61), does not convince the Court to the contrary. In that filing, Defendants note that they have received Plaintiffs' Claim Construction Issue Identification, which states that "the terms of the patents-in-suit should be given their plain and ordinary meaning as understood by a person of ordinary skill in the art." (D.I. 61, ex. 1) However, regardless of whether Plaintiffs will propose at a *Markman* hearing that the Court adopt a particular construction of the term-at-issue, there are many ways in which the consideration of the type of briefing and evidence put forward at the *Markman* stage can be relevant to the Court in analyzing this term. Such information might assist the Court in ultimately determining that it is appropriate to (1) not construe the term (2) utilize a proposed alternative construction that may later be put forward by Plaintiffs (3) adopt the Court's own construction or (4) adopt the Defendants' proposed construction.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878–79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006).

The parties are directed to the Court's Standing Order In Non-Pro Se Matters For Objections Filed Under Fed. R. Civ. P. 72, dated November 16, 2009, a copy of which is available at http://www.ded.uscourts.gov.

Because this Report & Recommendation may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Report & Recommendation. Any such redacted version shall be submitted no later than **December 12, 2012** for review by the Court. The Court will subsequently issue a publicly-available version of its Report & Recommendation.

Dated: December 5, 2012

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE